

REMARKS

Claims 24-43 are pending. Editorial revisions have been made to improve the clarity of the claims. Claim 24 has been limited to liquid dairy products and to passing said products not more than 3-5 times through the homogenizer. Descriptive support for this amendment is found in the original claims, page 9 (liquid dairy products) and Fig. 1 (3 and 5 times). Support for the amendments to Claims 25-30 is found on page 9, lines 11-et seq. (various dairy products) and on page 12 (raw milk). Accordingly, the Applicants do not believe that any new matter has been added.

Rejection—35 U.S.C. §112, first paragraph

Claims 24-43 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description. As requested by the Examiner, the Applicants provide below a chart showing descriptive support for the limitations in the claims.

<u>Limitation</u>	<u>Support</u>
not more than three to five times	Page 6, line 23 exemplifies “not more than 3 times and five times”. One would immediately envisage the intermediate value of 4 times from this description.
increased flow rate and pressure drop bring about sheer stresses, cavitation, turbulence, and/or impingement	page 8, lines 3 to 7
about 100 MPa to 300 MPa	page 13, lines 6 to 24 and on Figure 4
25 to 60°C	page 13, lines 9 to 13
microorganisms such as fungi	page 6, lines 8 to 11
at least 2 to 8 logs fewer microorganisms	Figure 4 to Figure 7

Regarding the use of phosphate buffer in Figure 1, Figure 1 is presented as a model, illustrating the effect of the claimed process on milk and is validated by Figs. 4-7.

Accordingly, in view of the descriptive support indicated above, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §112, second paragraph

Claims 31 and 32 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above.

Rejection—35 U.S.C. §102

Claims 24-26, 28-32 and 34-43 were rejected under 35 U.S.C. 102(b) as being anticipated by Klopp et al., DE 3903648A. The Applicants refer back to the arguments in their last response and expand on them below. The process of Klopp does not anticipate the invention for the following reasons:

In general, Klopp does not disclose a **dynamic high pressure homogenizer**, such as that exemplified by the Emulsifex-C5 and Emulsifex C160. The underlying concept of the Klopp patent (sonication) is totally different from the invention (dynamic high pressure homogenization). The claimed process requires the use of dynamic high pressure to create shear stress, cavitation, turbulence and/or impingement to homogenize a liquid.

In contrast, Klopp uses sonication in order to create the cavitation necessary for homogenizing the liquid. This is particularly well illustrated on page 2 of Klopp, 5th paragraph, when it is stated that:

In experiment, it has been shown to be particularly favourable if an energy input into the liquids is set between 10 000 Ws to 150 000 Ws per litre.

And on the same page on the 8th paragraph:

To produce cavitation, an oscillator immersed in the liquid, for example, can be used. It is advantageous if the liquid is also conducted past the

oscillating surface. This can also take place in that the oscillating structure is located within a tube at which or around which, the liquid flows through the tube (emphasis added).

What is called a homogenizing valve in Klopp is in fact only acting as a compression means to push the liquid through the valve, so the liquid would be exposed to the sonication. Thus, Klopp insists that the sonication is essential to the homogenization of the liquid, especially on page 3, where it is stated that

This takes place particularly effectively if, at the same time, an area of compression space acts as a sonic source” and, on paragraph 10 of the same page, “For practical application cases, it has proved to be particularly advantageous, if sound with a frequency between 20 kHz and 1 MHz is introduced into the liquid.

It is therefore clear that Klopp cannot anticipate claims presented herein since its homogenization process is performed by sonication, unlike the homogenization of the present claims which is performed by dynamic high pressure.

Assuming *arguendo* that Klopp was interpreted to refer to cavitation not produced by an oscillator, it still would not disclose with sufficient specificity the method of the present invention, because it does not disclose dynamic high pressure homogenization of a liquid dairy product or reduction of bacteria since Klopp is directed to a process of inactivating viruses (see first page) in liquids such as cell cut which are not food products. While page 4, line 6, refers to the milk industry, it is referring to eliminating viruses (bacteriophages) from cell cultures used as starter cultures. Removal of bacteriophages would prevent bacteriolysis of bacteria used to ferment milk products in the milk industry.

In view of the differences between the homogenizers used by Klopp, in the homogenization conditions and process steps, and the lack of specificity in describing a method for treating a liquid dairy products, such as milk, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §103

Claims 24-32 and 34-43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,232,726, in view of Kuchеров, U.S. Patent No. 6,019,947. The cited prior art does not render the invention obvious, because it does not suggest or provide a reasonable expectation of success for the claimed invention.

Clark et al. describes ultra high pressure homogenization of fruit juices (col. 1, lines 8-9) and does not disclose or suggest the application of this procedure to liquid dairy products of the present application. Fruit juices do not have the protein component of dairy products, and thus high pressure homogenization of fruit juice does not provide a reasonable expectation of success for using similar methods on milk products. The Applicants refer to Lacroix et al., Food Res. Int. 38, 569-576 (2005) and Tahiri et al., Food Res. Int. 39, 98-105 (2006)(both attached) for their description of the effects of dynamic high pressure homogenization of fruit juices.

On the other hand, high pressures are well known in the art to induce protein denaturation, and one of ordinary skill in the art would have had no motivation whatsoever to apply the method described by Clark to dairy products, since the reasonable expectation would have been that most proteins would be denatured by this treatment. One of the inventive aspects of the present invention is that milk proteins are mostly under casein micelle form and that those micelles resist the high pressures of the present invention. Other milk proteins not under micelle form can adhere to the casein micelles and therefore be protected from denaturation. Such a surprising property of milk proteins can not have been expected from the ordinary skilled man in the art at the time of filing of the present application.

Moreover, Clark describe a method in which the apparatus is made of stainless steel, which was the usual standard at the time the application was filed (1993). Such stainless steel apparatus are well known in the art as not being able to handle pressure over 15,000 psi, even though Clark mention in column 2, line 55 that the pressure can be over 15,000 psi. Hence, the maximum pressure at which the method of Clark can effectively be used is of 15,000 psi (bout 100 MPa). The use of pressure greater than 15,000 psi requires apparatus made of ceramics, such as the one described in the present application and marketed in the late 90's. Ceramics apparatus can handle pressure from 100 MPa to 300 MPa without any problems. There is no suggestion in Clark to make a ceramic apparatus.

Furthermore, there is no motivation to combine Clark with Kuchеров, especially for the removal of bacteria from dairy products containing denaturable proteins.

Kuchеров et al. describes an apparatus for liquid sterilization by high-pressure dynamic cavitation (abstract). However, the device of Kuchеров is only directed to the processing of small volumes in a relatively long residence time (0.9 ml in 170 sec.), while the present application is teaching a method having a yield of about 160 litres in one hour. One of ordinary skill in the art would easily appreciate that such a technique cannot be used for achieving the yield of the present application. Moreover, Kuchеров also teaches that recirculation of the liquid can be performed up to 40 times, which is unconceivable to perform on dairy products such as milk. Milk proteins and components would not resist such a high number of recirculation without being altered and degraded.

Furthermore, the 3 to 5 repetitions claimed herein are sufficient to reduce the number of microorganisms present by at least 2 to 8 logs. In comparison, Kuchеров shows in Figure 13 that a number of repetitions comprised between 3 and 5 do not even achieve a microorganism's reduction by 1 log. Therefore, the combination of those two references is not enabling for the pressure range and the volumes necessary for the realization of the

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present invention as well as for the efficiency of the present method. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §103

Claim 33 was rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al., U.S. Patent No. 5,232,726, in view of Kuchеров, U.S. Patent No. 6,019,947, and further in view of Emulsiflex, website and in view of page 7, line 4 of the Response dated 1/17/06. The Applicants traverse this rejection for the reasons expressed above and since none of the cited prior art suggests or provides a reasonable expectation of success for use of a high pressure homogenizer, especially for the removal of bacteria from dairy products. Such use would not have been suggested to one of ordinary skill in the art, since he or she would have immediately discarded the potential use of such a homogenizer for its expected effect on protein denaturation. Accordingly, this rejection may now also be withdrawn.

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CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Thomas M. Cunningham', with a long horizontal flourish extending to the right.

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